February 15, 2023

STAT Medical Devices
% Mr. Kevin Walls, MBA
Principal Consultant
FDA Compliance Group
33 Golden Eagle Lane
Littleton, Colorado 80127

Re: K223815
Trade/Device Name: ONE DROP Lancing Device
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood lancets
Regulatory Class: Class II
Product Code: QRL,QRK
Dated: December 20, 2022
Received: December 20, 2022

Dear Mr. Walls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Carr -S

for Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223815

Device Name

ONE DROP Lancing Device

Indications for Use *(Describe)*

The One Drop Lancing Device is for use with One Drop branded Lancets to collect capillary blood for testing purposes from the fingertip. The One Drop Lancing Device is for single patient use in a home setting.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

One Drop Lancing Device

510(k) Summary

Name and Address of Sponsor

STAT Medical Devices
2056 N.E. 153rd Street
North Miami Beach, FL 33162
Hemel Mariano (Quality Manager)
305-945-0011 Ext. 312
hmariano@statdevices.com

Establishment Registration Number: 1058955

Document Date: 02/01/2023

Name and Address of Official Correspondent

FDA Compliance Group
33 Golden Eagle Lane
Littleton, Colorado 80127
Contact: Mr. Kevin Walls, MBA
Telephone: 720-962-5412
Fax: 720-962-5413
Email: kevin@reginsight.com

Device Information

Trade Name: One Drop Lancing Device

Common Name: Blood Lancets & Lancing Devices

Classification Name: Blood lancets

Regulation Number: 878.4850, Class II

Product Code: QRL, QRK

Device Description

The One Drop Lancing Device is used with the One Drop branded Lancet, which was cleared under 510(k) K221383 under the device name MedtFine Blood Lancet

The intended use of the One Drop Lancing Device is to function as a single-person reusable device that holds a lancet to puncture the skin for capillary blood sampling for blood glucose testing. It is not to be used for assisted blood draws by healthcare providers or at healthcare provision sites.

The One Drop Lancing Device is made of ABS plastic and aluminum plated with Polycarbonate and SUS304 stainless-steel springs. The One Drop Lancing Device has 5 depth-setting choices. The device requires that the lancing device end cap be removed, a single lancet be inserted into the lancet holder and then the lancing device end cap placed back onto the device. The user is able to set the desired depth penetration level

by moving the depth selector. The lancing device is then cocked by pulling the back end of the device away from the lancet body. To fire the device the firing button is depressed. Once the lancet has been fired it moves forward to pierce the patients' test site with the lancet. After piercing the skin, the lancet then travels back into the housing of the lancing device. The lancing device end cap is removed and then the lancet is safely removed by using the ejector sleeve feature. It is then disposed of into an appropriate container. The body and lancing device end cap are cleaned with disinfecting wipes and allowed to air dry after each use and disinfected per the IFU, as needed.

The lancing device end cap is cleaned after every use and when visibly dirty and before disinfection. Disinfection is performed between each use. Cleaning involves use of a disinfecting wipe to wipe the outside of the lancing device end cap, followed by wiping dry. The device is cleaned & disinfected using Super Sani-Cloth Germicidal Disposable Wipes and allowed to air dry.

Indications for Use

The One Drop Lancing Device is for use with One Drop branded Lancets to collect capillary blood for testing purposes from the fingertip. The One Drop Lancing Device is for single patient use in a home setting.

Legally Marketed Predicate Device

Predicate #: K214022

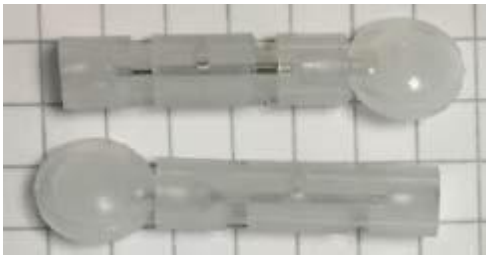
Predicate Trade Name: Accu-Chek Softclix Blood Lancing System

Product Code: QRL, QRK

Similarities and Differences between Candidate Device and Predicate Device:

	Predicate Device – Accu-Chek Softclix Blood Lancing System K214022	Candidate Device – One Drop Lancing Device
Device Description	Accu-Chek Softclix Blood Lancing Device uses Accu-Chek Softclix Lancets to obtain a drop of blood from a fingertip or alternate sites using the Accu-Chek Softclix Alternate Site Testing (AST) Cap.	One Drop Lancing Device uses the One Drop branded Lancets to obtain a drop of blood from a fingertip.
Intended Use	Accu-Chek Softclix Blood Lancing Device System is intended for the hygienic collection of capillary blood for testing purposed from the side of a finger and from alternate site, such as the palm, the upper arm, and the forearm.	One Drop Lancing Device is intended for the hygienic collection of capillary blood for testing purposed from the side of a finger.

Indications for Use	The Accu-Chek Softclix Blood Lancing System is intended for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the palm, the upper arm, and the forearm. The sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of. This system is for use only on a single patient in a home setting. This system is not suitable for use by healthcare professionals with multiple patients in a healthcare setting.	The One Drop Lancing Device is for use with One Drop branded Lancets to collect capillary blood for testing purposes from the fingertip. The One Drop Lancing Device is for single patient use in a home setting.
Number of Uses	Base (lancing device) – multiple use Lancet – single use	Base (lancing device) – multiple use Lancet – single use
Device Images	Lancing Device & AST Cap:	Lancing Device: 

	  Lancet: 	One Drop branded Lancet (K221383): 
Lancet Sterility	Yes, gamma irradiation	Yes, gamma irradiation
Needle	0.4mm (28G); beveled cut with 3 facets	0.21mm (33G); beveled cut with 3 facets
Depth Adjustment	11 levels by twisting cap	5 depth settings by sliding lever
Mechanical Loading	Spring-driven	Spring-driven
Load and Firing	Load by pressing priming button when lancet is inserted, Fire by pressing release button	Load by advancing lancet into holding section and pushing down, Fire by pressing release button

Anatomical Sites	Fingertip Ball of hand (palm) Upper arm Lower arm	Fingertip
Sharps Injury Prevention	Lancets are covered by a sterile barrier cap until twisted off before use. Until firing, the lancet is contained within the lancing device housing. Immediately after firing, the lancet is automatically retracted back into the housing. An ejector sleeve can then be pulled forward for contactless disposal of the lancet.	Lancets are covered by a sterile barrier cap until twisted or pulled off before use. Until firing, the lancet is contained within the lancing device housing. Immediately after firing, the lancet is automatically retracted back into the housing. An ejector sleeve can then be pulled forward for contactless disposal of the lancet.

Non-Clinical Testing Summary and Conclusions

Non-clinical bench testing was performed to ensure predetermined criteria were met and the special controls (21 CFR 878.4850) were satisfied. This includes mechanical design verification and validation testing in order to ensure the risks were appropriately managed in addition to verifying that the device continued to meet the specified requirements. Physical testing included dimensional measurements, function reliability drop test, piercing depth test, and cock force test. Biocompatibility was evaluated through a battery of tests to meet ISO 10993-1 requirements.

Compatibility between the One Drop branded Lancets and the One Drop Lancing Device was tested previously under 510(k) K221383 under the device name MedtFine Blood Lancet, which is the same device as the One Drop branded Lancets.

Conclusion

The intended use, technology, non-clinical testing, and functionality of the One Drop Lancing Device demonstrate a substantially equivalent safety and effectiveness profile to the predicate device.